HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 27 1999

WARNING LETTER

Ref: OC: I1-1833

via FEDERAL EXPRESS

Mr. William Cheng, President
Optical Instrument Manufacturing Co., Ltd.
No. 1 Lane 253, Chung Cheng Road
Shun Lin
Taipei, Taiwan

Dear Mr. Cheng:

This letter is to advise you of items of noncompliance with the Federal performance standard for laser products (21 CFR1040.10. and 1040.11) encountered during laboratory testing of the radiation output and evaluation of labeling of laser pointers. These pointers were identified as model LK series being produced by either Optical Instrument Manufacturing Co., Ltd., or Hsiang Long Precision Industrial Co., Ltd.

The pointers tested were collected from a shipment of 7000 (2000 black and 5000 gold) key-chain style pointers being imported by The B & F Systems Inc., 3920 S. Walton Walker Blvd., Dallas, Texas 75236. Six samples were collected from each of two entries assigned entry number FB2-01011796-9 (black key-chain style) and entry number FB2-0101827-2 (gold key-chain style). The following noncompliant items were noted:

1. 21 CFR1040.10(c) and 1040.10(d): Classification of laser products. One of six black pointers tested was misclassified in that the radiation output of this unit tested 7 mW thereby exceeding the Class IIIa limit of 5 mW. As a result, this unit was Class IIIb and failed to comply with the requirements of the standard applicable to Class IIIb laser products. It should be noted that the radiation output of another black pointer was found to be 5.4 mW, just under the allowable measurement uncertainty of plus 10 percent.

2. 21 CFR 1040.11(b): Alignment laser products. Laser pointers are alignment laser products and are limited to a maximum radiation output of 5 mW. The unit testing 7 mW was noncompliant with respect to this requirement.

All of the pointers evaluated were noncompliant with respect to the following items:

1. 21 CFR 1040.10(g): Labeling requirements. The required warning logotype label was not affixed to the products as required by 21 CFR 1040.10(g)(10). Inclusion of this label in the package with instructions for the purchaser to affix the label to the product is not acceptable. The manufacturer must permanently affix this label to the product at the time of certification. Further, all certified laser products must be in compliance with the standard at the time they are presented for entry into U.S. commerce.

2. 21 CFR 1040.10(g)(5): Aperture label. Aperture labels were not affixed to the product as required.

3. 21 CFR 1010.2: Certification. Labels or tags certifying that the products comply with the standard were not affixed to the product as required. A statement of certification was included in the user instruction for the black but not the gold pointers.

4. 21 CFR 1010.3: Identification: Labels containing the information specified in the regulations were not affixed to the products although this information was included in the user instruction for the black pointers. Optical Instrument Manufacturing Co., Ltd., was identified as the manufacturer of the black pointers. We note however, that the boxes in which the gold pointers were packaged indicated the manufacturer to be Hsiang Lang Precision Ind., Co. No address was given, and a complete address is required for the location of the manufacturer.

The gold key-chain pointers were also noncompliant with the following items:

21 CFR 1040.10(b): User information. The warning logotype reproduced in the "User Instructions" for the gold pointers was incorrect. A Class II "Caution" logotype and incorrect wording was shown in the user instruction for this Class IIIa laser product. The logotype shown identified the products as being a "Class III Laser Product" when the intended class of the pointer was Class IIIa. Class IIIa laser products require a "Danger" logotype with applicable wording on this label which is to be affixed to the pointer. Further, the location on the product of the required warning labels was not shown in these instructions as required by 21 CFR 1940.10(h)(iii).

We understand that these products have been refused entry into the United States. Therefore, we will not require submission of notification or a corrective action plan (CAP) for this particular shipment.

However, you are hereby advised that section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968), prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

Based on the noncompliances cited above, it is apparent that the manufacturer(s) of these laser products has failed to establish and maintain a quality assurance and testing program that assures compliance of laser products with the standard. Therefore, by this letter, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), disapproves the quality control and testing program for all laser products produced by or for Optical Instruments Manufacturing Co., Ltd., and Hsiang Long Precision Industrial Co., Ltd., This action is taken under authority of the Act.

This disapproval means that your firm is prohibited by Section 534(h) and 538 of the Act from:

1. Certifying the electronic products manufactured under the disapproved testing program,

2. Introducing or importing laser products into the United States commerce which bear false and misleading certification, that is products certified under the testing program which has been disapproved products, and

3. Introducing or importing into U.S. commerce any product that does not have a certification label permanently affixed as required by 21 CFR 1010.3.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U.S. of any electronic product if it appears that the product fails to comply with the Act, that the subject products comply with the performance standard, and the testing program is in accordance with good manufacturing practices. Optical Instrument Manufacturing Co., Ltd., is now included on FDA Import Alert #95-04. Hsiang Long Precision Industries Co., Ltd., will also be included on this alert. This alert can be found on internet web site:

www.fda.gov/ora/fiars/ora_import_ia95-04.html.

If you intend to export laser products to the U.S. in the future they must be in compliance with the standard. Therefore, to resolve this matter you must submit all the information required under 21 CFR 1002.10 so that CDRH can determine that your company is in compliance with the act and that the subject products comply with the standard and that your testing program(s) are in accordance with good manufacturing practices. The CDRH will

inform you whether your submittal is satisfactory. Enclosed is a copy of HEW Publication (FDA) 76-8036, "Quality Control Practices for Compliance...". You may find this publication helpful for evaluating the completeness and effectiveness of your quality control and testing program.

Submit your response to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. Should you have any questions on these requirements, please contact Frank Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Spears for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enc: HEW Publication (FDA) 76-8036

CC: The B&F Systems, Inc.
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